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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/995,419 | 11/26/2001 | Jim McWhir | 096/004 | 1905 |

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| EXAMINER |
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WOITACH, JOSEPH T

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/995,419 | Applicant(s) MCWHIR ET AL. | |
| | Examiner Joseph T. Voitach | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 23-47 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-12, 23-47 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 01 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

This application filed November 26, 2001 claims benefit to provisional applications: 60/253,357, filed November 27, 2000; 60/253,443, filed November 27, 2000; and 60/253,395, filed November 27, 2000.

Applicants' amendment filed April 16, 2004, has been received and entered. Claim 1, 8, 10-14 have been amended. Claims 23-47 have been added. Claims 1-12, 23-47 are pending.

Election/Restriction

Applicant's election with traverse of Group III in Paper No. 11 was acknowledged. The traversal that Groups I and III should not be restricted was found persuasive and groups I and III were rejoined. Further, the election of species was withdrawn.

Newly added claims 23-47 are drawn to the elected invention and will be included in the examination.

Claim Objections

Claim 10 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.

The amendment to the claims has obviated the basis of the rejection.

Specification

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The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example page 18, line 38.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 5-8 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a differentiated cell by obtaining a genetically altered undifferentiated stem cell comprising a heterologous construct that selectively expresses a cell surface antigen in an undifferentiated cell, differentiating said cells, an selecting for the cell surface antigen expressed, does not reasonably provide enablement for expressing post translational modifying enzymes such as glycosyltransferases, and identifying and selectively using complement to lyse said undifferentiated cells is withdrawn.

Applicants arguments and supporting information of various known enzymes and lectins provides adequate evidence that one of skill in the art had the available materials to practice the claimed invention. More specifically, as argued by Applicants, Examiner agrees that the activity of any particular glycosyltransferase is specific enough to reasonably predict the new

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carbohydrate-ligand that would be formed. As a consequence, one of skill in the art would know the appropriate ligand and/or antibody to use in the context of the claimed methods.

Claims 1-15, 23-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case at issue are the specific promoters and types of stem cells required to practice the claimed methods. The claims broadly support the use of any type of stem cell, and as supported by the specification this includes cells from the brain, liver, hematopoietic system, and mesenchymal cells (pages 11-12). To practice the claimed methods an artisan is required to be in possession of promoters that are selectively active in these cell types, but not cells differentiated therefrom. The specification highlights the use of TERT and OCT-4 promoters, which are only active in embryonic stem cells (see page 19, lines 28-42 also evidenced by *Pesce et al. Stem Cells* 19:271-278, 2001, *Liu et al. Amer. J. Resp. Cell Mol Biol.* 26:534-540, 2002, and *Reubinoff et al. Nature Biotech* 18:399-404, 2000), and promoters of cell surface proteins found only on embryonic stem cells (page 20, lines 4-7). Finally, the specification teaches that particular elements can be identified and analyzed by its gene expression or by analysis of reporter constructs (page 20, lines 10-15). The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described

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in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). However, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. In this case, while OCT-4 and the TERT promoter can be used in embryonic stem cells, the specification fails to describe other specific promoters for use in embryonic stem cells, and fails to teach any promoters that could be used in cells isolated from specific tissues such as the brain or the liver.

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula

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from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

In this case, because Applicants have failed to provide an adequate written description of the materials used in the compositions and methods as claimed and because there is no evidence that Applicants possessed any promoters beyond those disclosed and/or known in the prior art, the rejected claims fail to meet the written description requirement under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10, 11, 12 and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

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The amendments to the claims have obviated the basis of each of the specific rejections.

Claims 31-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in claim 31 recites the limitation "the differentiated cells" in step c) lack antecedent basis. There is insufficient antecedent basis for this limitation in the claim. It is noted that step b) indicates that the hES cells are differentiated, however this would lead a composition of cells, undifferentiated and differentiated. Further, there is no indication of what was specifically done to affect the cells, so it is unclear what the differentiated cells represent, i.e. one type of differentiated cell or a variety of different cell types. In this case, it is unclear what specific differentiated cell is to be formulated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 14, 2-4, 9-10, 15 rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.* (US Patent 6,146,888) is withdrawn.

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The amendment to the claims to include additional method steps not taught by Smith et al. has differentiated the claimed invention from that taught in the prior art.

Conclusion

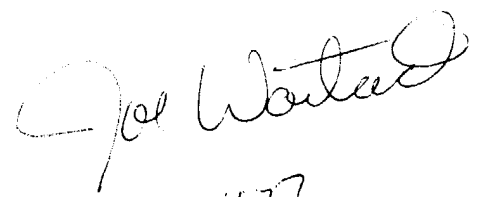
No claim is allowed. The claims are free of the art of record because while the art supports using identification and purification techniques for the isolation of stem cells, it does not disclose using heterologous markers expressed preferentially in these cells in conjunction with differentiation protocols to selectively exclude the presence of stem cells in the final composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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